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DATE: October 28, 2004

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Patent Application Serial No.: 10/031,423
Application Filing Date: 01/16/02
Applicant: VITOLONE et al.

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TO: Examiner L. A. Alexander, Art Unit 1743
U.S. Patent and Trademark Office

Re: Submission of copy of claims

FROM: Curtis L. Schrandt, Esq. (o/b/o R. Neil Sudol)

NUMBER OF PAGES INCLUDING THIS PAGE: 7

COMMENTS:

As discussed in telephonic communication this date, please find the current set of claims in the above-identified application.

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CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper and the papers referred to herein are being facsimile transmitted to the Patent and Trademark Office to 703-872-9306 on October 25, 2004.



Curtis L. Schrandt

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OCT 28 2004

Applicants : Vitolone et al.
U.S. Application No. : 10/031,423
U.S. Application Filed : 01/16/02
Title of Invention : PROCESS FOR THE QUANTITATIVE DETERMINATION OF ALKALOIDS SUCH AS COCAINE IN A SOLID SAMPLE AND REAGENT FOR USE IN SUCH PROCESS
Examiner : L. A. Alexander Art Unit : 1743

Commissioner for Patents
P.O. 1450
Alexandria, VA 22313-1450

SUBMISSION OF PENDING CLAIMS

SIR:

Pursuant to a telephone communication on October 15, 2004, between the undersigned attorney and the Examiner in the above-identified application, applicants transmit herewith a clean version of all pending claims as they existed prior to the Office Action mailed July 19, 2004. The Office Action should have considered the enclosed set of claims.

Also enclosed is a copy of the official Filing Receipt and original returned post card receipt in corroboration of this submission.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

Dated: October 25, 2004

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M38-025

SUBSTITUTE CLAIMS (ARTICLE 34 AMENDED CLAIMS) FILED WITH APPLICATION, AS FURTHER AMENDED BY PRELIMINARY AMENDMENT DATED JANUARY 16, 2002 (ALSO FILED WITH APPLICATION)

CURRENT STATE OF CLAIMS IN THE APPLICATION PRIOR TO ANY OFFICE ACTION (NON-MARKED UP VERSION)

1. A screening-type process for the quantitative determination of cocaine and other alkaloids which are present in a solid sample which includes the steps of:
 - a) preparing a solid sample in a finely divided or powdered form;
 - b) selecting a liquid reagent providing constant concentration of hydroxyl groups suitable for extracting and transforming cocaine into benzoylecgonine and for extracting other similar substances;
 - c) extracting cocaine and other similar substances contained in the sample and transforming the extracted cocaine into benzoylecgonine by maintaining the sample completely immersed in said liquid reagent at a temperature ranging from 10°C to 250°C for a period of time ranging from few seconds to 48 hours; and
 - d) analysing the liquid separated from the solid sample to determine the concentration of benzoylecgonine contained in said liquid with respect to the cut-off limit using a conventional screening kit for the determination of the said substance in urine.
2. Process according to claim 1, wherein said solid sample is a sample of hair.
3. Process according to claim 1, wherein said temperature is ranging from 100°C to 150°C.
4. Process according to claim 1, wherein said period of time is ranging from 15 minutes to 24

hours.

5. Process according to claim 1, wherein said temperature is maintained at 100°C for 1 hour.
6. Process according to claim 1, wherein said liquid reagent is an ammonia buffer comprising 0.2 M $(\text{NH}_4)_2\text{HPO}_4$ with the addition of 5 ml of 25% NH_4OH to each liter thereof.
7. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of from 0.0001M to 5 M.
8. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.03M to 0.5 M.
9. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.04M to 0.33 M.
10. Process according to claim 1, wherein the analyzed samples are arranged in increasing order of concentration of cocaine or other alkaloids.
11. Process according to claim 1, wherein the samples are subjected to confirmation analyses with standard techniques such as GC or GC/MS.
12. Process according to claim 2, wherein each hair sample is made of about 50mg to 300 mg of

finely divided and/or powdered hair.

13. Process according to claim 1, wherein said liquid reagent is a solution comprising a solute selected among aluminum hydroxide, barium hydroxide octahydrate, benzyltriethylammonium hydroxide, benzyltrimethylammonium hydroxide, calcium hydroxide, phenylhydrargirium hydroxide, lithium hydroxide, lithium hydroxide monohydrate, magnesium hydroxide, potassium hydroxide, potassium hydroxyantimoniate, sodium hydroxide, sodium hydroxide monohydrate, strontium hydroxide octahydrate, tetramethylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, dissolved in a solvent selected among ethanol, methanol, water, monobasic ammonium phosphate, ammonium acetate, ammonium benzoate, ammonium bicarbonate, ammonium bichromate, ammonium bisulphate, ammonium bromide, ammonium carbamate, ammonium carbonate, ammonium citrate bibasic, ammonium chromate, ammonium iodide, molibdate, ammonium monovanadate, ammonium nitrate, ammonium oxalate monohydrate, ammonium persulphate, ammonium sulphate, ammonium sulphamate, ammonium sulphite, ammonium sulphide, ammonium tartrate, ammonium thiocyanate, ammonium thioglycolate, ammonium thiosulphate, ammonium chloride, sodium phosphate monobasic, sodium phosphate bibasic, potassium phosphate monobasic, potassium phosphate bibasic.

14. Diagnostic kit for carrying out the process according to claim 1, comprising a liquid reagent with constant concentration of hydroxyl groups suitable for extracting cocaine and other alkaloids and transforming cocaine into benzoylecgonine, and a conventional screening kit for the determination of said metabolite in urine samples.